Remarks

The Office Action dated March 23, 2004 has been carefully reviewed and the following comments are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Summary of the Office Action

1. Claims 32-33 have been withdrawn from consideration as being directed to a non-elected invention.

2. Claims 20 to 31, 34 to 36 and 40 to 44 were rejected under 35 U.S.C. 102(e) purportedly for being anticipated by Williams (U.S. Patent 5,731,284).

Rejection under 35 U.S.C. 102(e)

Claims 20 to 31, 34 to 36 and 40 to 44 were rejected under 35 U.S.C. 102(e) purportedly for being anticipated by Williams (U.S. Patent 5,731,284). The Examiner purports that the cited reference discloses a method of administering GDNF in an amount effective to treat neuronal injury and therefore, the disclosed administration inherently affects sodium channel current flow.

Applicants submit that the Examiner has not provided a reasonable basis in fact that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. In establishing a *prima facie* case of inherent anticipation, an Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessary flows from the teachings of the applied prior art (see *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. Inter. 1990) and MPEP 2112). In this case, Williams *et al.* disclose that GDNF may be used to treat injury of or degeneration of basal forebrain cholinergic neurons and it is to this method that the claims of the '284 issued. Pain not mentioned in the '284 patent, other than in the context that the prior art teaches that NGF induces severe pain when administered peripherally (see column 4, lines 54 to 55). The Examiner has provided no basis that the administration of GDNF to a patient with injury or degeneration of basal forebrain cholinergic neurons is even experiencing pain, as required by the claims, let alone having pain alleviated. In the absence of such a demonstration, Applicants submit that the Examiner has not met his burden of establishing a *prima facie* case of inherency.

Furthermore, Applicants submit that the skilled artisan would not even have expected that a neuronal growth factor like GDNF would be useful for the treatment of pain. In the background section of the cited reference, two studies are cited where administration to humans of NGF, a related neurotropic factor, resulted in severe muscle pain and that such effects may disallow potentially efficacious use of such neurotropic factors (see column 4, lines 51 to 65). Clearly, such studies are an indication that the skilled artisan would not have expected neurotropic factors such as GDNF to be useful for the treatment of pain, when in fact the prior art disclosed that they caused pain upon administration to humans.

Applicants also submit that the cited reference does not each and every limitation of the claimed invention and therefore does not anticipate the rejected claims. Applicants note that even if a claimed method comprises steps identical to those of a method practiced in the prior art, and the same result would have been achieved in the prior art method (which is not the case here), the accidental or unwitting achievement of that result cannot constitute anticipation (see *In re Marshall*, 578 F.2d 301 (CCPA 1978)).

In *Marshall*, the claims were directed to a weight control process comprising the administering of an anesthetic such as oxethazaine to inhibit release of hormones, thereby preventing release of pancreatic enzymes that would otherwise digest food passing through the digestive tract. The cited reference was the Physician's Desk Reference, which disclosed use of oxethazaine for treatment of esophagitis, gastritis, peptic ulcer and irritable colon syndrome, and disclosed that this anesthetic inhibited release of the acid-stimulating hormone, gastrin. The Court held that the cited reference did not disclose every material element of the claimed subject matter because the claims were directed to a weight control process and nothing in the cited reference remotely suggested taking oxethazaine to lose weight. The court added that "[i]f anyone ever lost weight by following the PDR teachings it was an unrecognized accident" (*ibid* at 302).

The cited reference in the present application makes no disclosure which establishes a relationship between GDNF and pain reduction. Rather the cited references discloses the administration of GDNF for treatment of patients with neuronal damage due to Alzheimer's disease. A word search of the published patents indicates that the term "pain" is only disclosed in two instances (see column 4, lines 55 and 61), and not in reference to GDNF, but in reference to NGF. Applicants submit that the cited reference does not anticipate the rejected claims because it does not disclose every material element of the claimed subject matter as the claims are directed to a method for treating pain, and nothing in the cited reference remotely suggests administration of GDNF for the treatment of pain as claimed.

Applicants respectfully request reconsideration of the subject application in view of the above remarks and withdrawal of the rejections. It is respectfully submitted that this application is now in condition for allowance. Should the Examiner believe it to be useful, an interview with the Examiner is respectfully requested in order to discuss the foregoing claims.

If there are any fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted
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